

In October 1999, Dr. Neal Lane, Assistant to the President for Science and Technology, reinforced the request that NBAC examine the federal system of oversight. This report addresses the basic purpose, structure, and implementation of research oversight. We recommend broad, strategic changes to the oversight system. This report is not intended to be a rewrite of federal regulations but instead to provide the guidance, direction, and justification for change. Providing Comments to the Draft Report.

You may provide written comments electronically or through mail or fax. Electronic submissions (by email or by website) are preferred as they will be processed more efficiently. The following are addresses for submitting comments: e-mail: nbac@od.nih.gov, NBAC website: www.bioethics.gov, mail: 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, fax: (301) 480-6900.

If your comments are not postmarked by February 17, 2001, we can not guarantee they will be given full consideration.

#### **TO RECEIVE A COPY OF THIS DRAFT REPORT**

**CONTACT:** National Bioethics Advisory Commission, 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, telephone (301) 402-4242, fax number (301) 480-6900, or visit the website at www.bioethics.gov.

**SUPPLEMENTARY INFORMATION:** The President established the National Bioethics Advisory Commission (NBAC) on October 3, 1995 by Executive Order 12975 as amended. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council, its Chair, the President, and other entities on bioethical issues arising from the research on human biology and behavior, and from the applications of that research.

Dated: December 13, 2000.

**Eric M. Meslin,**

*Executive Director, National Bioethics Advisory Commission.*

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**BILLING CODE 4167-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

[60Day-01-08]

#### **Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506 (c)(2)(A) of the Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

#### **Proposed Project**

Linking Epidemiologic Research to Disease Prevention: A Pilot Program to Test Approaches for Communicating Increased Risk of Cervical Cancer to Female Workers in the Dry-Cleaning Industry —NEW—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

The National Institute for Occupational Safety and Health (NIOSH) has conducted worker notification formally since 1988. This program informs workers in NIOSH-conducted epidemiological studies about the study results and hence, of their risks. The intervention research to be conducted under this application will extend the risk communication beyond the mortality study cohort (an aging and mostly retired cohort) to similarly exposed women, younger and still employed.

Several studies, including one conducted at NIOSH, have documented elevated mortality from cancer among dry cleaning workers. Some of the cancers involved—most notably cervical cancer—can be successfully treated if detected early. Thus, along with better hazard control, better secondary disease prevention is urgently needed to help women workers already exposed. Exiting NIOSH procedures for notifying workers about the agency's research findings seem unlikely to reach the larger at-risk population of women dry cleaners who were not actually study subjects.

The ultimate purpose of this research is to increase understanding of how to encourage medical screening among workers at risk. The project has two main objectives: (1) To assess descriptively the feasibility and potential public health benefits of a broader than usual approach to NIOSH worker notification about occupational health risks, based on results of NIOSH epidemiologic research; and (2) to determine whether a follow-up reminder about the importance of medical screening makes a significant difference in the notified workers' long-term health behavior.

The primary study population will consist of a minimum 300 current female dry cleaning workers in New York City (ages 18-65), selected from the membership list (a respondent universe of 375) from the dry cleaners' local labor union. A separate population of 100 former dry cleaning workers randomly selected from a cohort list of approximately 226 surviving women dry cleaners in a NIOSH cohort mortality study will provide descriptive data only and will not be included in the data analysis of the primary group of currently employed dry cleaners. All study participants will be mailed a packet of risk information from NIOSH, along with a letter of endorsement of the study from the local union in New York, encouraging participation in the study. The risk information packet will include the NIOSH mortality study results as well as other information about cancer and cancer screening, with a special emphasis on cervical cancer screening.

Brief (15-minute) telephone interviews will follow the mailed notifications to workers and will be used to evaluate (1) the effects of an intervention (mailed written notification materials) on post-intervention cervical cancer screening behaviors; and (2) the effects of a reminder message mailed six months after the initial notification.

The effect of the first intervention will be measured by comparing the pre- and post-intervention screening behaviors

for the year prior to the intervention. The effect of the second intervention will be evaluated experimentally (using a control group), measuring the screening behaviors from the time of the reminder letter to the Time-2 interview 6 months later, compared to the screening behaviors at the Time-1 interview.

These intervention evaluations will address barriers to cervical screening and also will allow insight into the following questions:

1. Does the outreach message have a long-term impact concerning the use of cancer screening services (message retention and actual screening behavior)?

2. Does receiving a screening reminder affect message retention and actual screening behavior?

The total cost to all respondents (current dry cleaners and surviving dry cleaners from the NIOSH mortality study) in the two-year study is estimated at \$2733.46 based on an average wage of \$10.79 per hour.

Respondents	No. of respondents	No. of responses	Avg. burden Per response (in hrs.)	Total burden (in hrs.)
Year 1 .....	400	1	20/60	133.3
Year 2 .....	360	1	20/60	120.0
Total .....	.....	.....	.....	253.3

Dated: December 8, 2000.

**Nancy Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention, (CDC).*

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00D-1584]

**Draft Guidance for Industry on Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals.” The draft guidance is intended to provide information on procedures for requesting an exemption or deferral in accordance with the final rule that established standardized format and content requirements for the labeling of over-the-counter (OTC) human drug products.

**DATES:** Submit written comments on the draft guidance by February 20, 2001. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information

Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled “Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals.” This is one of a series of guidances intended to help manufacturers, packers, and distributors implement the final rule establishing standardized format and content requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and content requirements for the labeling of all OTC drug products, including drug-cosmetic products. This rule is intended to standardize labeling for all OTC human drug products to help consumers read and understand the product labeling and use these products safely and effectively.

This draft document is intended to provide guidance on the format and procedures for submitting requests for

exemptions and deferrals from the requirements of the rule.

This draft guidance is being issued consistent with FDA’s good guidance regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency’s current thinking on exemptions and deferral procedures related to the labeling of OTC human drug products (21 CFR part 201). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00-32195 Filed 12-18-00; 8:45 am]

**BILLING CODE 4160-01-F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-5013]

**Guidance for Industry on Labeling Over-the-Counter Human Drug Products Using a Column Format; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.